life years saved, and the incremental cost effectiveness ratio. Only direct medical costs in 2003 United States dollars were considered.

Implementation Strategy: A model was built based on the following assumptions: standard of care chemotherapy for previously untreated metastatic colorectal cancer was considered to be 5-FU plus leucovorin plus either oxaliplatin (FOLFOX) or irinotecan (FOLFIRI); improvement in median overall survival, time to progression, and increased incidence of adverse events with the addition of bevacizumab was based on published trials; duration of treatment was equal to time to progression; cost of therapy beyond disease progression was not included in the cost effectiveness or budget impact analyses; and budget impact analysis was based on the assumption that 40% of those patients initially presenting with metastatic colorectal receive treatment at UT M.D. Anderson Cancer Center (50% on FOLFOX and 50% on FOLFIRI). Non FDA-indicated use of bevacizumab was not included in the budget impact analysis.

Direct medical costs of treatment with FOLFOX are $140,114, and $270,049 for FOLFOX/bevacizumab, incremental cost of bevacizumab is $129,935. Comparable numbers are $68,519 for FOLFIRI, and $165,330 for FOLFIRI/bevacizumab, incremental cost is $96,811. Using published outcomes measurements of 0.39 life years saved (LYS) with the addition of bevacizumab to either FOLFOX or FOLFIRI, the incremental cost effectiveness ratio was $333,167 per life year saved for the FOLFOX and $248,233 per LYS for FOLFIRI. For our expected annual patient population of 250, the annual budget impact of chemotherapy and bevacizumab for our institution was projected to be $25,804,250.

This model, along with a clinical monograph, was presented to the P&T Committee at the same time as the vote for bevacizumab's inclusion onto formulary. Bevacizumab was added to the formulary without restriction for its use with regards to its FDA-indication.

Results: We reviewed MDACC usage for the first six months of 2006. We had 411 unique patients, with 237 (60%) receiving the drug for a gastrointestinal (GI) malignancy. Of these 237 GI patients, there were 185 unique patients (78%) who received bevacizumab for colorectal cancer, of which only 132 patients (71%) received 5-FU/leucovorin plus bevacizumab plus either oxaliplatin or irinotecan. This means that out of the 411 unique patients who received bevacizumab at MDACC, only 132 patients (32%) actually used it in the manner our model detailed. In order to estimate the accuracy of our model, we used these 132 patients as the basis to check our model's validity and accuracy. For colo-rectal cancer patients receiving bevacizumab added to either FOLFOX or FOLFIRI regimens, our model is accurate to within 5% ($26.4M, actual versus $25.2M, model).

However, there are some caveats to the institution-wide validity of the model. We multiplied the number of patients actually seen in the first six months by two to estimate an annual number. Our model excludes 279 patients (68%) who did not receive bevacizumab for colo-rectal cancer. Determining the institutional reimbursement pattern for the patients who received bevacizumab is ongoing.

Lessons Learned: For any drug that shows an improvement in overall survival for a solid tumor, we should expect MDACC usage to surpass the usage estimated by a model based solely on its FDA indication. However, building a model to incorporate all possible uses, without controlling its prescribing, is an impossibility, so we base our models on the FDA-indication(s) for the drug. Patient outcomes for non-FDA approved usages should be captured in prospective clinical trials, and included in the model when they can be quantified.

A structured formulary management process, which includes an economic impact analysis section, is an appropriate platform to delineate the cost effectiveness of new oncology products. In an era of rising costs, coupled with dwindling resources, a coherent plan for the allocation of resources is an imperative for any institution that strives to provide continued patient care.

CASE STUDY POSTER PRESENTATIONS

PCASE1

APPLICATION OF PHARMACOECONOMICS TO DOD'S ANTILIPIDEMIC-1 UNIFORM FORMULARY DECISION

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Organization: Department of Defense (DoD) Pharmacy and Therapeutics (P&T) Committee

Problem or Issue Addressed: In August 2006, the DoD P&T Committee made Uniform Formulary (UF) recommendations to the Director, TRICARE Management Activity (TMA), for the Antilipidemic-1 therapeutic class. This was the Committee's most significant recommendation since the inception of the UF for three reasons: 1) this class is ranked number one in terms of DoD expenditures (>$500M in fiscal year [FY] 2006; 9% of Rx spend); 2) the joint DoD/Veteran's Administration (VA) contract for Zocor (simvastatin), the workhorse statin for the DoD (65% of total days of statin therapy across the Military Health System [MHS] in FY 2006), was about to expire; and 3) competition within the class was about to increase as a result of impending generic availability of simvastatin.

Goals: The DoD P&T Committee's overall goal was to identify a therapeutic mix of Antilipidemic-1 agents that best met the majority of the clinical needs of the DoD population at the lowest cost to the MHS. To accomplish this goal, three primary objectives were identified: 1) maintain simvastatin as the workhorse statin and preserve current market share; 2) include an agent capable of achieving ≥45% LDL reduction, and 3) recommend non-formulary status for agents not cost-effective relative to other agents in the class.

Outcome items used in the decision: The 32 CFR Part 199 (Civilian Health and Medical Program of the Uniform Services [Champus] / TRICARE: Implementation of the Pharmacy Benefits Program) implements section 701 of the National Defense Authorization Act for FY 2000. This regulation "establishes procedures for the inclusion of pharmaceutical agents on a UF based upon the relative clinical effectiveness and relative cost-effectiveness." Following this guidance, the DoD P&T Committee makes UF recommendations based upon both an evidence-based clinical effectiveness review and a cost effectiveness review of agents within the therapeutic class. Four different cost effectiveness models were constructed to analyze the relative cost effectiveness of statins capable of achieving ≥45% LDL reduction [atorvastatin 40 and 80 mg; rosuvastatin 10, 20, and 40 mg; ezetimibe/simvastatin 10/20, 10/40, and 10/80 mg; and simvastatin 80 mg]:

1) The Annual Cost per 1% LDL Decrease model compared cost effectiveness of the high % LDL lowering agents on annual cost per 1% LDL decrease.
2) The Annual Cost per Patient Treated to Goal model compared cost effectiveness of these agents on annual cost per patient successfully treated to NCEP.
3) The Medical Cost Offset Model compared cost effectiveness of these agents based on their predicted outcomes and total predicted health care expenditures for CHD and CHD risk-equivalent patients.

4) The Cost per Event-Free Patient model, based on the results of the IDEAL Trial, compared cost effectiveness of the agents included in that trial—high-dose (80 mg) atorvastatin vs. low-dose (20–40 mg) simvastatin.

In addition, a budget impact analysis was performed to assist the Committee in determining which group of agents best met the majority of the clinical needs of the DoD population at the lowest cost to the MHS.

Implementation Strategy: On 23 October 2006, the Director, TMA signed a decision paper accepting the DoD P&T Committee's Antilipidemic-1 UF recommendations, with an implementation date of 1 February 2007. Accordingly, atorvastatin, fluvastatin immediate and extended release, pravastatin, simvastatin, lovastatin immediate & extended release, lovastatin/niacin, ezetimibe/simvastatin, niacin immediate and extended release, and ezetimibe were maintained as formulary on the UF and rosuvastatin and atorvastatin/amlodipine were classified as non-formulary under the UF.

Results: The DoD P&T Committee met its primary goal by providing a broad array of Antilipidemic-1 agents sufficient to meet the clinical needs for the majority of the DoD population. It also met two of its primary objectives: 1) two agents were included on the UF, in addition to simvastatin 80 mg, capable of achieving ≥45% LDL reduction (atorvastatin and simvastatin/ezetimibe); 2) agents determined not to be cost-effective relative to other agents in the class were designated as non-formulary on the UF. Whether or not the DoD is successful in preserving simvastatin market share will be closely monitored as this decision is implemented.

Lessons Learned: Presentation of results from multiple cost effectiveness models—which focus on different outcomes and use different methods, but are all based on an evidence-based review of the clinical and pharmacoeconomic literature—increased the Committee's confidence in making recommendations in this class. The BIA, which incorporated factors not included in the cost effectiveness models, further refined the Committee's understanding of the expected benefits resulting from various formulary scenarios.

PCASE2

EVALUATION OF LEVALBUTEROL USE IN A >600 BED TEACHING HOSPITAL

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Organization: University of Maryland Medical Center

Problem or Issue Addressed: Excessive use of a high cost non-formulary drug.

Goal: To evaluate the use of Levalbuterol in a teaching hospital and to determine need for inclusion (if any) on the hospital formulary.

Outcomes items used in the decision: Levalbuterol is FDA-approved for the treatment or prevention of acute bronchospasm in adults, adolescents, and children aged 6 or older with reversible obstructive airway disease. Our institution recently realized a significant increase in the purchasing of this agent, which prompted an intensive evaluation of the prescribing habits surrounding levalbuterol. The purpose of our study was to identify the indications for levalbuterol use, evaluate the appropriateness of dosing, determine contraindications to alternate therapies, and recognize adverse events, if any, associated with levalbuterol use.

Implementation Strategy: This evaluation was a criteria-based, retrospective evaluation of all patients for whom levalbuterol was prescribed over an 18 month period. All patients were identified from computerized pharmacy records. Patient therapy was evaluated via physician progress notes, laboratory reports, and physician orders. Purchase data was determined via the pharmacy's computerized medication inventory management system.

Results: The majority of levalbuterol use was in pediatric patients (27%), followed by cardiac surgery patients (17%) and internal medicine service patients (14%). Indications of shortness of breath or respiratory distress associated with various disease states and medical procedures comprised 38% of levalbuterol use. 35% of use was in COPD (20%) and asthma (15%) combined. The majority of patients received levalbuterol for <3 days at a dosing frequency of less than every 6 hours. 80% of patients received albuterol therapy prior to levalbuterol administration. No adverse events related to levalbuterol use were reported.

Conclusions/Lessons Learned: Our study reveals that patients are prescribed levalbuterol for a variety of indications, most of which are non-FDA approved uses. Patients at high risk for cardiac side effects, including pediatric and cardiac surgery patients, are likely to receive levalbuterol. Prescribers typically utilize levalbuterol after patients failed to improve on or experienced side effects to albuterol. Dosing frequency exceeded approved labeling and established guidelines in most cases. Determined there may be a need to include levalbuterol on the hospital formulary restricted to pediatric patients meeting certain specific criteria.

PCASE3

USING OUTCOMES RESEARCH TO SUPPORT ANITBIOTIC SELECTION

Basskin L

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Organization: Healthsouth Sunrise Rehabilitation Hospital

Problem or Issue Addressed: Increasing costs of Antibiotics

Goals: To determine the reasons for increased costs of antibiotics at a rehabilitation hospital, and to determine whether interventions were necessary to reduce costs and improve outcomes.

Outcomes items used in the decision: a) organism susceptibility per cultures when compared to empiric antibiotics selected; b) proportion of empiric antibiotics subsequently determined to be resistant; c) incidence of intravenous medications when patient was receiving oral medications; d) duration of antibiotic therapy when patient was asymptomatic (and compared to recommended duration of therapy); and e) appropriate dose and interval based on patient's renal function.

Implementation Strategy: Random sampling of patients receiving antibiotics used in the previous 12 months.

Results: 1. More cost-effective medication were available empirically in the treatment of UTI and Cellulitus. 2. Selection of resistant antibiotics occurred infrequently, but when encountered, the change in antibiotics was delayed at times. 3. Some asymptomatic patients who were receiving all other medications oral could have been switched from IV to PO antibiotics. 4. Some excess duration because of antibiotic use at prior facility. 5. Dose and interval appropriate with some adjustments require for renal function, readily accepted by physicians.

Conclusions/Lessons Learned: Antibiotic selection needs some intervention. Three part program will be implemented: 1. Some restrictions on availability of ordering IV antibiotics without ID consult. 2. Physician education as to proper dose, interval, and frequency. 3. A pharmacy-run infectious disease service to guide empiric selection and ensure quick review of cultures.